[redacted]

P-18-0212

Chemical Name: [redacted]

CASRN: [redacted]

ASSIGNMENTS	NAME	DATE
SAT Chair	Doritza Pagan-Rodriguez	06/26/18
HH Hazard Assessor (A)	Keith Salazar	06/26/18
HH Hazard QC Reviewer (A)	William Irwin	06/28/18
HH Risk Assessor FOCUS (B)	Cal Baier-Anderson	07/05/18
HH Risk QC Reviewer (B)	Keith Salazar	07/10/18

	Human Health Report Status:	DATE COMPLETED
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	[redacted]	
	[redacted]	

7/31/18: updated to correct risk calculation for worker and general population inhalation risks – initially used incorrect calculator. CBA
11/14/18: Corrected typographical errors in calculator K. Salazar
11/26/18: Corrected typographical errors in calculator K. Salazar

[redacted]

1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard.

Based on the hazard determination and available quantitative and qualitative risk information, EPA concludes that there is risk for the PMN substance for health effects via inhalation. The risk estimates for this chemical are for the intended conditions of use.

1.1 Hazard Summary

- Absorption of the neat material is nil all routes based on pchem; if in solution, absorption of the LMW fractions is poor all routes based on pchem.
- There are no data on the PMN substance or close analogs representing the PMN substance as a whole. The hazard assessment is based on data on the cation and information provided in the SDS.
- Concern for portal of entry effects (GI, lungs, eyes, dermal contact), systemic effects (reduced body weight, ocular effects, oral exposures) and potential developmental toxicity (oral and inhalation exposure).

1.2 Risk Summary

1.2.1 Workers

- Risks were identified for workers for health effects (decreased body weight) via inhalation based on analog data (MOE = 80, Benchmark MOE = 100, Fold Factor = 1.3, Recommended APF = 10).

- Risks for irritation for workers via ocular, respiratory and dermal exposure cannot be quantified due to lack of dose-response information for this hazard. However, exposures can be controlled by the appropriate use of personal protective equipments (PPE), such as gloves, eye protection, and a respirator with an APF of 10. EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the submitter, in a manner adequate to protect them. Therefore, EPA does not expect unreasonable risk for the irritation endpoint.

- Risks were not identified for workers for reproductive/developmental effects via dermal exposure, based on analog data (MOE_{dermal} = 2660, Benchmark = 1000).

1.2.2 General Population

Risks were not identified for general population for portal of entry, systemic toxicity or reproductive/developmental effects via inhalation or oral exposure, based on analog data (adult MOE=9,760,000, infant MOE= 2,320,000; benchmark MOE=1000; inhalation MOE=3.0E+06; benchmark MOE=100).

1.2.3 Consumers

Consumer risks were not evaluated because consumer uses were not identified as conditions of use.

[redacted]

1.3 Potentially Useful Information:

1.3.1 Assumptions and Uncertainties

Absorption of the PMN is based on p-chem properties

There are no measured data on the PMN substance itself.

Health effects are based on [redacted] of the PMN.

1.3.2 Potentially Useful Information

Potentially useful information would inform understanding of:

Absorption

Specific target organ toxicity

Developmental, reproductive toxicity

[redacted]

2 HUMAN HEALTH HAZARD- PART A

2.1 Chemistry Summary

PMN: P-18-0212	Submitter:	Allnex USA Inc.			Manu.	Import
Max. PV (KG):	[redacted]		Binding Option Marked:			X
MW: 4453	1.2	% < 500	6.2	% <1000	CASNO	[redacted]

[redacted]	Prop.	Meas.	Est.
	MP		
	BP		
	Pres.		at 760 mm Hg
	VP		<0.000001
	S-H2O		Dispersible
	log P		

[redacted]	Analogs: [redacted]
USE: Resin for coatings applied to glass substrates; the resin improves the coatings' appearence and adhesion. All analogs are binder resins for coatings. Polymer Exemption case (E1).	other_uses No other uses found.

2.1 SAT Summary

2.1.1 Absorption

Absorption of the neat material is nil all routes (pchem); if in solution, absorption of the LMW fractions is poor all routes (pchem).

2.1.2 SAT Health Summary

Concern for portal of entry effects, systemic effects and potential developmental toxicity based on data on cation.

2.1.3 PMN Data (Study summary, POD)

None provided

[redacted]

2.1.4 **Analog Data** (analog, structure, study summary, POD)

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(38) ANALOGS:

PMN or CAS No.	Chem. Name	Structure	TSCA Y/N
[redacted]			Y
			N
			N

[redacted]

HEALTH: Absorption nil all routes based on pchem;

- concern for lung toxicity if inhaled based on high molecular weight
- low-moderate concern for toxicity;

[redacted]

- TOXNET indicates that transient corneal opacity, changes in respiratory and olfactory epithelium of the nasal cavity, body weight loss and potential developmental toxicity effects (only one fetal variation was elevated in the high dose group) have been observed in animal studies.

- From ECHA database:
  - OECD 413: NOAEC of 24 ppm (87.6 mg/m^3) based on 13-week subchronic study in F344 rats exposed to 0, 8, 24, 76ppm CMEA for 6hr/day, 5 days/week for 13 weeks that observed histopathologic lesions of the respiratory and olfactory epithelium.
  - OECD 421/414: DMEA by whole-body exposure in pregnant F344 rats at 0, 10, 30, or 100ppm during GD 6-15 resulted in maternal toxicity (reduced body weight, reduced weight gain, ocular effects (GHS category 2A for eye irritation)) at 30 and 100ppm with no evidence of embryonic or fetal toxicity. Fetal body weights/litter were increased at 100ppm. Developmental NOAEC is 30 ppm. Maternal NOAEC is 10ppm (36.4 mg/m^3).
- [redacted] (OECD 414/421)

  The test substance was administered to time-mated female rats orally by gavage from GD 6 through GD 19 (prenatal study part) or GD 6 through PND 3 (postnatal study part). The dose levels were 0 (control: 10 animals), 300 (dose group 1: 10 animals) and 600 mg/kg body weight/day (dose group 2: 20 animals).

  For the prenatal study part, selected dams of each group (5 animals of the control group, 5 animals of dose group 1 and 10 animals of dose group 2) were sacrificed on GD 20; dams and fetuses were examined.

  For the postnatal study part, the remaining dams were allowed to litter and rear their pups until PND 4. On PND 4, all pups were sacrificed and examined grossly.
  - LOAEL of 300 mg/kg-day based on stomach erosions/ulcera in dams, increased post-implantation loss, increased resorptions at 300 mg/kg-day

2.1.5 **Other Information** (SDS, structural alert or component of interest, basis, etc.)

SDS:

2. HAZARDS IDENTIFICATION

LABEL ELEMENTS

Hazard Statements
Precautionary Statements
Hazards Not Otherwise Classified (HNOC), Other Hazards
Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS

Component / CAS No.	%	GHS Classification	Carcinogen
Dipropylene glycol methyl ether 34590-94-8	<= 5.2	Flam. Liq. 4 (H227)	-

11. TOXICOLOGICAL INFORMATION

Likely Routes of Exposure: Skin, Eyes, Oral.

PRODUCT TOXICITY INFORMATION

ACUTE TOXICITY DATA

oral	rat	Acute LD50	> 2000 mg/kg
dermal	rabbit	Acute LD50	> 2000 mg/kg
inhalation	rat	Acute LC50 4 hr	> 5 mg/l (Dust/Mist)

LOCAL EFFECTS ON SKIN AND EYE

Acute Irritation	dermal	Not irritating
Acute Irritation	eye	No data

ALLERGIC SENSITIZATION

Sensitization	Skin	No data
Sensitization	respiratory	No data

GENOTOXICITY

Assays for Gene Mutations

Ames Salmonella Assay	No data

[redacted]

Notes:

- At pre-SAT/SAT, the PMN was not identified as a lung toxicant based on pchem properties, lack of structural alerts and because it is not expected to behave as a surfactant in the lungs.
- PMN substance contains about [redacted] cation moiety and [redacted] acid.

2.1.6 Exposure Routes of Interest

Route of Interest	
X	Inhalation:
X	Dermal:
X	Ingestion:

2.2 Human Health Category (From US EPA 2010 document)

Chemical Category: Not applicable

2.3 Point of Departure Selected and Basis

2.3.1 POD for [redacted] ([redacted] of PMN) for inhalation exposures

POD type: NOAEC
POD Value: 36.4 mg/m^3
POD Chemical: [redacted]
POD Route: inhalation
POD Hazard Endpoint: Maternal toxicity (reduced body weight, reduced weight gain, ocular effects)
POD Basis: Lowest available POD for inhalation exposures
POD Benchmark MOE: 100
Reference: ECHA database accessed 06/26/18

2.3.2 POD for [redacted] ([redacted] of PMN) for oral exposures

POD type: LOAEL
POD Value: 300 mg/kg-day
POD Chemical: [redacted]
POD Route: oral
POD Hazard Endpoint: stomach erosions/ulcera in dams, increased post-implantation loss, increased resorptions
POD Basis: Lowest available POD for oral exposures
POD Benchmark MOE: 1000
Reference: [redacted]

[redacted]

3 HUMAN HEALTH RISK (PART B)

3.1 USES and EXPOSURES

3.1.1 Uses

Resins

3.1.2 Worker Exposure

3.1.2.1 Inhalation

Negligible

Particulates
Potential Dose Rate: [redacted] mg/day over [redacted] days/yr

3.1.2.2 Dermal

Exposure to Liquid at [redacted] concentration
High End:
> Potential Dose Rate: [redacted] mg/day over [redacted] days/yr
> Lifetime Average Daily Dose: [redacted] mg/day over [redacted] days/yr
> Average Daily Dose: [redacted] mg/day over [redacted] days/yr
> Acute Potential Dose: [redacted] mg/day over [redacted] days/yr

3.1.3 General Population Exposure:

3.1.3.1 Drinking Water

- Drinking water ingestion with ADR as high as **3.99e-04 mg/kg/day** and LADD as high as **1.33e-05 mg/kg/day**

3.1.3.2 Fish

- Fish ingestion exposures are not calculated if a chemical is not released to surface water or the bioconcentration factor is negligible.

3.1.3.3 Air/Inhalation

- Inhalation from fugitive air releases with ADR as high as **3.66e-02 mg/kg/day** and LADD as high as **8.67e-04 mg/kg/day**
- Inhalation from fugitive air releases with ADR as high as **3.66e-02 mg/kg/day** and LADD as high as **8.67e-04 mg/kg/day**

3.1.4 Consumer Exposure

No identified consumer uses.

[redacted]

3.2 RISK CALCULATIONS

Absorption of the neat material is nil all routes based on pchem; if in solution, absorption of the LMW fractions is poor all routes based on pchem.
Oral, stomach erosions/ulcera in dams, increased post-implantation loss, increased resorptions, **LOAEL = 300 mg/kg bw/day**
Inhalation, Maternal toxicity (reduced body weight, reduced weight gain, ocular effects), **NOAEL = 36.4 mg/m3**

3.2.1 Worker Calculations

Worker Margin of Exposure (MOE) Calculations using Animal inhalation POD and Engineering Report PDR

	Animal or Human POD			Worker Exposure				Human Breathing Rates						Benchmark MOE	Endpoint Type
Exposure Route	POD Conc. mg/m^3	POD Period hrs/day	POD Duration days/wk	Exposure mg/day Potential Dose Rate (PDR)	Total Worker Breathing Volume for PDR Exposure Period m^3	Worker Exposure Duration Hours/Day	Exposure Duration Days/Wk	Default	Worker	Structural Alert as % of PMN	POD Conc - Duration & Breathing Rate Correction $Scenario_{HEC}$ mg/m^3	Exposure TWA mg/m^3	**Margin of Exposure MOE**	100	NOAEL
Inhalation	[redacted]			[redacted]				[redacted]			[redacted]	[redacted]		Fold Factor =	1.3

Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR

	Animal or Human			Human							Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/day Potential Dose Rate (PDR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Body Weight kg	Exposure mg/kg-day	Structural Alert as % of PMN	Margin of Exposure MOE	1000	LOAEL
Dermal	[redacted]			[redacted]				[redacted]		**2664.0**	[redacted]	

[redacted]

3.2.2 General Population Calculations

Population Margin of Exposure (MOE) Calculations using Animal Inhalation POD and Exposure Report ADR

	Animal or Human			Human						Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/kg-day Acute Dose Rate (ADR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Multiplier for Susceptible Subpopulations	Structural Alert as % of PMN	Margin of Exposure MOE	1000	LOAEL
Drinking Water	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	9,764,671.42	[redacted]	
Drinking Water	[redacted]		[redacted]	[redacted]		[redacted]		[redacted]	2,324,921.77		

General Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR

	Animal or Human POD			Population Exposure						Benchmark MOE	Endpoint Type
Inhalation Exposure Scenario	POD Conc. mg/m^3	POD Period hrs/day	POD Duration days/wk	Exposure (24-hr conc.) (ug/m3)	Population Exposure Duration Hours/Day	Exposure Duration Days/Wk	Structural Alert as % of PMN	POD Conc - Duration Correction - $Scenario_{HEC}$ mg/m^3	**Margin of Exposure MOE**	100	NOAEL
Fugitive air	[redacted]			[redacted]				[redacted]	**3.0E+06**		

3.2.3 Consumer Calculations

Consumer risks were not evaluated because consumer uses were not identified as conditions of use.

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